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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,265      | 10/17/2001  | Bo Qiu               | 271/287             | 8579             |

34055 7590 10/15/2003

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| EXAMINER |
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CEPERLEY, MARY

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 10/15/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/982,265

Applicant(s)

QIU ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7 and 9-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7 and 9-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**1)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**2)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**3)** Claims 9, 10, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification to support the terms "two to two hundred units" and "four to twenty units". The only specific descriptions of "n", used in reference to the term "units", appear in Figure 3 (n = 8) and Figure 2 (n = 0.9 and 0.1 {unclear meaning since it would appear that "n" must be a whole number}).

**4)** Claims 1-3, 5-7, and 9-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the attachment of a single immunologically reactive substance through the single pendant amine group of a single "unit" as described in amended claim 1, does not reasonably provide enablement for the attachment of more than one immunologically reactive substance to a given unit. See the structure of claim 1 and the synthesis of Figure 2. There is no description in the specification of how to prepare any structure wherein the attachment of the immunologically reactive moiety is at any other position on the repeating unit. There is further no description of the "reporter moiety" of claim 14 being attached at any position other than R. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. It appears that the term "an attachment site..." in claim 1 should be "the attachment site for the immunologically reactive substance".

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Similarly, for claims 12 and 24, there is no enablement in the specification for the preparation of a "unit" which "carries more than one epitope". There is a single reactive amino group on the backbone of the  $\text{-NH-PEG-NH-CO-CH(NH)-CH}_2\text{-CO-}$  "unit" to which a single immunologically reactive substance can be attached (see the structure of claim 1 and the synthesis of Figure 2). There is no description in the specification of how to prepare any structure wherein the attachment of the immunologically reactive substance is at any other position on the repeating unit.

**5)** Claims 1-3, 5-7, and 9-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**a)** There is no written description in the specification of the term "R represents an attachment site for the one or more immunologically reactive substances" of amended claim 1.

**b)** There is no written description in the specification to support the subject matter of newly presented claim 14.

**c)** In claim 28, there is no written description in the specification of the "epitopes" being attached to any "linking molecule".

**6)** Claims 1-3, 5-7, and 9-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** The structure depicted in amended claim 1 is incorrect. The pendant side chain should be attached to the  $\text{-CH-}$  moiety of the repeating "unit" rather than the  $\text{-CH}_2\text{-}$  moiety (see page 2, line 35 and page 3, lines 5-20 of the specification). See also, claim 17.

**b)** The language of claim 1 is unclear and confusing. It is unclear what is meant by the term "R represents an attachment site". Does this mean that **i)** "R" is a functional group (e.g. a

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reactive thiol) or *ii)* "R" *per se* is "an immunologically reactive substance"? Definition *i)* would be inconsistent with the claim preamble defining "an immunological test kit comprising an immunologically reactive substance connected to an immunologically invisible carrier". Further, for definition *i)* it is unclear what the chemical nature of the "site" is.

*c)* Claim 15 describes improperly recites method steps in a product claim (not a product by process claim). The final product *per se* would be the same independent of when the reporter moiety was attached to the invisible carrier.

*d)* In claim 14, it is unclear what is meant by subparagraph (a). What is the situation if "other positions R of the copolymer units are NOT occupied by one or more immunologically reactive substances"? For step (b) it is not clear which position is meant by "a position other than at position R". See also, claim 26.

*e)* In claim 28, it is unclear where the "linking molecule" is attached to the "carrier".

*7)* Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no enablement in the specification for how to prepare compositions in which the "epitope" is attached at a position other than the "R" position as shown in the structure of claim 1.

*8)* Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

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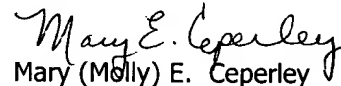
of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

October 14, 2003

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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